Remarks:

Claims 1-28 are pending in the application. In the Office action dated October 30, 2007, claims 1-28 were rejected under 35 U.S.C. § 103. Responsive to the Office action, claims 2 and 3 are cancelled and claims 1, 4, 5, 14, 15, and 28 are amended. In view of the amendments above, and the remarks below, Applicants respectfully request reconsideration of the application under 37 C.F.R. § 1.111 and allowance of the pending claims.

Rejections under 35 USC § 103

Claims 1-5, 8-15 and 21-28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cox et al. (U.S. 6,234,167) in view of Poole (U.S. 6,158,431).

The Examiner suggests that it would have been obvious to one of ordinary skill in the art at the time of the invention to have used a correction factor as used in the device of Cox et al. as taught by Poole in order to produce the desired performance characteristic in a given environment. Applicants respectfully disagree.

Applicants respectfully suggest that the Cox and Poole references, either singly or in combination, fail to disclose each and every element of the rejected claims. However, without acquiescing to the rejection, and in the interest of furthering the prosecution of the application, Applicants have amended claims 1, 4, 14, 15, and 28.

The amended claims are not rendered obvious by the cited references for at least the reason that each of the independent claims recites a dispenser having a medicament supply, an accumulator in fluid communication with the medicament supply, an ejector in fluid communication with the accumulator, a sensor that senses the pressure of the medicament in the accumulator, and a valve between the medicament supply and the accumulator that opens and closes in response to the sensed pressure in the accumulator, in order to regulate medicament pressure at the ejector. None of the cited references, either singly or considered in combination, disclose the elements of the rejected claims, as amended.

The Examiner asserts that Cox et al. discloses an inhaler having an accumulator, a pressure sensor to sense pressure in the accumulator, and a valve intermediate the medicament supply and the accumulator that is operated by the controller. Applicants respectfully disagree. The inhaler of Cox et al. is shown below.

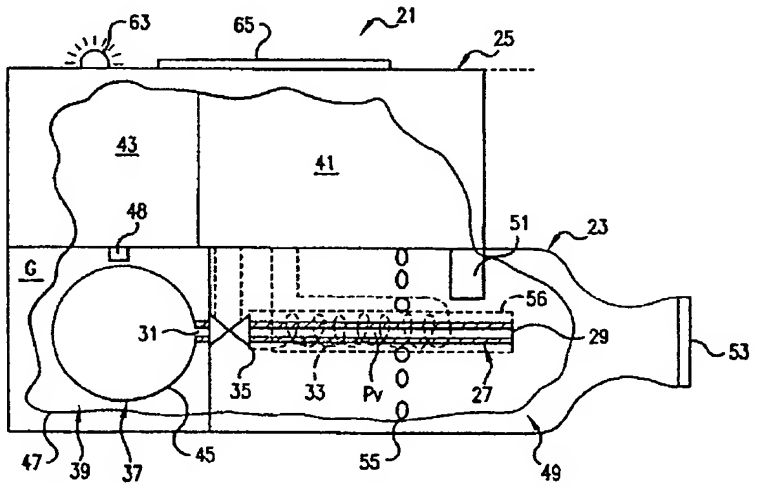

FIG.1

Cox et al. discloses an aerosol generator that includes a source of material 37, a tube 27 with an open end 29, a heater 33 for heating the tube, a valve 35 between the open tube 27 and the source of material 37, (see col. 3, line 61 to col. 4, line 9), and a pressure sensor 48 to sense the pressure of the gas G in chamber 47.

The Examiner asserts that open tube 27 is an accumulator, that 48 is a pressure sensor configured to sense the pressure in the accumulator, and that valve 35, when opened, would increase pressure in the accumulator. Applicants respectfully disagree with the Examiner.

Pressure sensor 48 is configured to sense the pressure of pressurized gas G within chamber 47. Since container 45, which contains the material to be dispensed, is flexible, the pressure measured by sensor 48 may be related to the pressure within the flexible container. However, pressure sensor 48 is on the opposite side of valve 35 from tube 27, which has been identified by the Examiner as the "accumulator". Therefore pressure sensor 48 is physically prevented from measuring the pressure with the "accumulator".

Furthermore, tube 27 is open-ended, with open end 29 being oriented toward mouthpiece 53. When the valve 35 is opened, material enters tube 27, and is then volatilized by heater 33. Since tube 27 is an open system, a pressure sensor within the tube would serve no purpose, as the pressure within the tube will always remain equal to outside pressure.

Additionally, valve 35 is not opened in response to a pressure sensed within tube 27. Rather, it is opened in response to activation of the inhaler by the operator (see col. 4, lines 25-37). When pressure sensor 48 detects a decrease in propellant pressure within chamber 47, the dispenser may keep valve 35 open longer when it has been actuated by the operator (see col. 5, lines 27-41), but in no case is valve 35 opened or closed by the controller solely in response to a measured pressure, and in no case is valve 35 opened in response to a pressure measured within the accumulator.

As discussed in Applicants' previous response, the Poole reference fails to disclose a device having an accumulator that is distinct from a therapeutic fluid supply, and fails to disclose any valve or regulator between the fluid supply and the ejector. Poole therefore necessarily fails to disclose an accumulator having a sensor for sensing pressure within the accumulator, and fails to disclose a valve between the fluid supply and the accumulator that is opened and closed in response to the sensed pressure.

The cited references fail to establish the *prima facie* obviousness of claims 1, 15, and 28 because they fail to disclose each and every element of the rejected claims. However, the cited references additionally fail to establish the *prima facie* obviousness of claims 1, 15, and 28 because they necessarily fail to provide a suggestion or motivation to combine and/or modify the references so as to arrive at the claimed invention.

Specifically, modification of the Cox et al. reference to create a pressurized accumulator, with a pressure sensor for measuring the medicament pressure within the

accumulator, would change the principle of operation of the Cox et al. dispenser, and destroy its stated utility.

The Cox et al. dispenser is intended to generate an aerosol from stored therapeutic material by dispensing the material into a tube, and heating the tube so that the material volatilizes and then expands out of the open end of the tube (see col. 3, lines 1-9). Modifying the Cox et al. dispenser so that the material is ejected under pressure would contradict the teaching of the reference itself, which recites the disadvantages of dispensing medicament through generated droplets (col. 1, lines 34-44) or through the use of a propellant (col. 1, line 45 to col. 2, line 6). One of ordinary skill in the art would not be led by the Cox et al. reference to change the principle of operation of the Cox et al. dispenser and dispense a medicament under pressure.

For at least these reasons, Applicants suggest that the Examiner has failed to establish the *prima facie* obviousness of the rejected claims, and respectfully request the withdrawal of the rejection of claims 1-5, 8-15 and 21-28 under 35 U.S.C. § 103.

Claims 6, 7 and 16-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Poole (U.S. 6,158,431), as applied to claims 1-5, 8-15, and 21-28, and further in view of Poole et al. (U.S. 5,278,626).

The Examiner suggests it would have been obvious to one of ordinary skill in the art at the time of the invention to use drop volume or weight for the performance characteristic instead of drop size for a more accurate determination of the amount of medication being delivered to the patient with each drop. Applicants respectfully

disagree, and suggest that the cited references fail to establish the *prima facie* obviousness of the rejected claims.

As discussed above, in view of the amendments to claims 1, 15, and 28, Applicants suggest that the Cox et al. and Poole references fail to disclose each and every element of the rejected claims, and fail to provide a suggestion or motivation to combine the references. Applicants additionally suggest that the Poole et al. reference similarly fails to disclose each and every element of the rejected claims, and also fails to supply the deficiency of Poole.

As discussed in Applicants' previous response, the system of Poole et al. is intended to be used for monitoring impurities in a liquid stream, and therefore does not include a fluid supply. Instead, "the system continuously samples a process line or slipstream to obtain a liquid sample" (see col. 4, lines 10-11). The sample liquid is not delivered to an accumulator, rather it is input to a precision micropump 10, and then delivered to a droplet generator 14 at a constant flow rate (see col. 4, lines 24-30).

Applicants therefore assert that Poole et al. fails to compensate for the deficiencies of the Cox et al. and Poole references, in that Poole et al. similarly fails to disclose a dispenser having a medicament supply, an accumulator in fluid communication with the medicament supply, an ejector in fluid communication with the accumulator, a sensor that senses the pressure of the medicament in the accumulator, and a valve between the medicament supply and the accumulator that opens and closes in response to the sensed pressure in the accumulator, in order to regulate medicament pressure at the ejector.

None of the cited references, either singly or considered in combination, disclose the elements of the rejected claims, as amended. Furthermore, none of the cited references provide sufficient motivation to modify the disclosed devices so as to arrive at the claimed invention. For at least these reasons, Applicants assert that the Examiner has failed to establish the *prima facie* obviousness of claims 6, 7 and 16-20, and they respectfully request the withdrawal of the rejection of the claims under 35 U.S.C. § 103.

Applicants believe that in view of the above amendments and remarks, this application is now in condition for allowance. Accordingly, Applicants respectfully request that the Examiner issue a Notice of Allowability covering the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to Examiner K. Matter, Group Art Unit 3771, Assistant Commissioner for Patents, at facsimile number (571) 273-8300 on January 29, 2008.

Christie A. Doolittle